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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/035,730      | 12/24/2001  | Kenji Sawa           | 10873.853US01       | 4134             |

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EXAMINER

MENON, KRISHNAN S

ART UNIT PAPER NUMBER

1723

DATE MAILED: 08/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/035,730

Applicant(s)

SAWA, KENJI

Examiner

Krishnan S Menon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3,4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sacco (US 5,059,173).

Sacco teaches a method of composing an infusion line comprising a spike unit (13,45) a main tube unit (12 at 27; line connecting 13, 43,40,30, etc.), an infusion filter unit (50), and a one-way valve unit (49), each unit being formed from one or more components (see figures), spike unit being at one end (see fig 1), and the distal end with respect to the spike unit having a connector for access to a patient (17). There is an extension tube as in claim 2 and 3, distal to the spike unit (12 at 17). Spike unit is connecting the infusion line to a supply source (14), main tube unit adjusts the length between the spike unit and other units positioned in the patient side (see fig 1), injection device (53) is positioned between the main tube unit and the extension tube and could be used for injecting medicines, infusion filter is positioned between the main tube unit and the extension tube (see 40), one-way valve is positioned on the opposite side of the spike unit with respect to the main tube unit to prevent back flow of infusion fluid (49), all as in claim 4. Claim 5 further adds the limitation of the extension tube positioned on the patient side allowing the infusion line to be held at hand of the patient (see fig).

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2. Claims 1-3 are rejected under 35 USC 102 (b) as being clearly anticipated by Urquhart et al (US 4,552,556)

Urquhart teaches a method of composing an infusion line comprising a spike unit (52-fig 2), a main tube unit (54) and an infusion filter unit (58; 142-fig 13; col 14 lines 13-31) as in claim 1. the method further comprises composing an extension tube to the end on the distal side with respect to the main tube unit as in claims 2 and 3 (23-fig 2)

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sacco (173) in view of Urquhart et al (US4,552,556).

Sacco teaches all the limitations of claims 1 and 2. Claims 6 and 7 add further limitations of spike unit including a spike and a drip chamber, which Sacco does not teach. [Sacco has the spike

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drip chamber down-stream of the filter, away from the spike unit]. Urquhart teaches a spike unit having a spike and a drip chamber (see 15-17, fig 1, and col 4 lines 65-68). It would be obvious to one of ordinary skill in the art at the time of invention to use the teaching of Urquhart in the teaching of Sacco to have the spike and the drip chamber together so that the drip chamber can be used to trap air in addition to adjust the flow rate, as taught by Urquhart. Additional limitations of claims 6 and 7 as taught by Sacco are: main tube having a clamp and connector (line 12 or 25 at 50), injection device including a connector and an injection port (52), infusion filter has a filter, tube and connector (40), one-way valve unit has a valve and a connector (49), extension tube has a tube and a connector (12 at 17).


### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S Menon whose telephone number is 703-305-5999. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L Walker can be reached on 703-308-0457. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Krishnan Menon  
Patent Examiner  
August 14, 2003

  
W. L. WALKER  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700